**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| BRAINTREE LABORATORIES, INC.,<br><br>Plaintiff,<br><br>v.<br><br>CYPRESS PHARMACEUTICAL, INC.,<br><br>Defendant. | ) | Civil Action No. 12-cv-6851-AJN<br>ECF Case |

**DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S COUNTERSTATEMENT TO PLAINTIFF BRAINTREE LABORATORIES, INC.'S RULE 56.1 STATEMENT OF MATERIAL FACTS**

Pursuant to Fed. R. Civ. P. 56 and L. Civ. R. 56.1, Defendant Cypress Pharmaceutical, Inc. ("Cypress") submits this Counter-Statement to Plaintiff Braintree Laboratories, Inc.'s ("Braintree") Rule 56.1 Statement of Material Facts in Support of its Opposition to Cypress' Motion for Summary Judgment of Noninfringement.

## GENERAL OBJECTIONS

1. Cypress objects to Braintree's Statement as improper under L. Civ. R. 56.1. Rather than reciting "additional material facts as to which it is contended that there exists a genuine issue to be tried," Braintree's Statement of Material Facts in Opposition to Cypress' Motion recites extensive *undisputed* facts, the majority of which are *irrelevant* to Cypress' Motion. L. Civ. R. 56.1(b). Moreover, the relevant facts recited by Braintree in support of its Opposition actually support Cypress' Motion for Summary Judgment of Noninfringement.[1]

**U.S. Patent No. 6,946,149**

1. Braintree is the lawful owner by assignment of U.S. Patent No. 6,946,149 ("the '149 patent"), entitled "Salt Solution for Colon Cleansing." *See* Dkt. No. 46-4, U.S. Patent No. 6,946,149, at Assignee (filed Apr. 30, 2002) (issued Sept. 20, 2005).

   **RESPONSE: Undisputed for purposes of Cypress' Motion.** Dkt. 41 ¶6.

2. The '149 patent was duly and legally issued by the U.S. Patent and Trademark Office ("the USPTO") on September 20, 2005. *See* Dkt. No. 46-4, U.S. Patent No. 6,946,149.

   **RESPONSE: Undisputed for purposes of Cypress' Motion.** Dkt. 41 ¶6.

[1] The facts set forth by Braintree in its Rule 56.1 Statement of Material Facts are referred to herein as "BMF."

3. Braintree requested ex-parte reexamination of the '149 patent on October 15, 2008. *See* Dkt. No. 46-3, U.S. Patent No. 6,946,149 Ex Parte Reexamination Certificate, at Reexamination Request; Brown Decl., Ex. 3

**RESPONSE: Undisputed.**

4. The USPTO issued a reexamination certificate for the '149 patent on June 30, 2009. *See* Dkt. No. 46-3, U.S. Patent No. 6,946,149 Ex Parte Reexamination Certificate, at Certificate Issued; Brown Decl., Ex. 4. [2]

**RESPONSE: Undisputed.**

5. Dr. Mark vB Cleveland and Dr. John S. Fordtran are the inventors of the '149 patent. *See* Dkt. No. 46-4, U.S. Patent No. 6,946,149; Brown Decl. Ex. 2 at BRTSUP00000240, U.S. Patent No. 6,946,149 Certificate of Correction.

**RESPONSE: Undisputed** that Dr. Mark vB Cleveland and Dr. John S. Fordtran are listed as inventors on the face of the '149 patent Certificate of Correction.

6. The '149 patent discloses and claims the discovery by Dr. Fordtran and Dr. Cleveland that aqueous, hypertonic, low-volume, balanced formulations of poorly-absorbable sulfate salts could induce purgation of the colon while avoiding clinically significant electrolyte shifts in patients. *See* Dkt. No. 46-4, U.S. Patent No. 6,946,149.

**RESPONSE: Undisputed for purposes of Cypress' Motion**, but Cypress objects to BMF 6 because it is an ambiguous and incomplete description of the '149 patent disclosure and claims. Dkt. 46-4. No response is required regarding what is

[2] References in this document to the "Brown Decl." are to the Declaration of Jennifer Brown in Support of Braintree Laboratories, Inc.'s Opposition to Cypress Pharmaceutical, Inc.'s Motion for Summary Judgment of Noninfringement, Dkt. No. 51.

"claimed" in the '149 patent since such a determination is not a fact, but a legal conclusion which is determinative of the present motion.

7. Claims 15, 18-20 and 23 (hereinafter "the asserted claims") of the '149 patent do not use the term "cleansing." *See* Dkt. No. 46-3, U.S. Patent No. 6,946,149 Ex Parte Reexamination Certificate, at Certificate Issued; Dkt. No. 46-3.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.**

8. All of the asserted claims of the '149 patent use the term "purgation." *See* Dkt. No. 46-3, U.S. Patent No. 6,946,149 Ex Parte Reexamination Certificate, at Certificate Issued.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.**

9. All of the asserted claims of the '149 patent require compositions "for inducing purgation." *See id.*

**RESPONSE:** No response is required regarding what the asserted claims of the '149 patent "require" since such a determination is not a fact, but a legal conclusion.

10. The '149 patent discloses examples, Solutions A-E, which were given in two 165 ml administrations. *See* Dkt. No. 46-4, at 5:48-55.

**RESPONSE:** **Undisputed.** Further, the '149 patent describes "the ingested experimental solutions" (*i.e.*, Solutions A-E) as "330 ml in volume." Dkt. No. 46-4 at 5:64-65.

11. The sodium phosphate based solutions of the prior art described in the '149 patent were associated with dangerous side effects, including severe electrolyte disturbances, heart and kidney failure, and death in certain cases. *See* Dkt. No. 46-4, U.S. Patent No. 6,946,149 at 4:23-40.

**RESPONSE: Undisputed for purposes of Cypress' motion, but irrelevant for purposes of Cypress' motion.**

**The SUPREP New Drug Application and Exclusivity**

12. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). *See* SF 1[3]; Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022372&TABLE1=OB_Rx.

**RESPONSE: Undisputed.**

13. NDA No. 22372 was approved by the U.S. Food and Drug Administration ("FDA") on August 5, 2010. *See* SF 2; Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022372&TABLE1=OB_Rx.

**RESPONSE: Undisputed.**

14. SUPREP is an osmotic laxative containing sodium sulfate, potassium sulfate and magnesium sulfate. *See* SF 3; Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022372&TABLE1=OB_Rx.

**RESPONSE: Undisputed.**

15. The FDA-approved indication for SUPREP is cleansing of the colon in preparation for colonoscopy in adults. *See* SF 4; Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=022372&TABLE1=OB_Rx.

[3] References to "SF" in this document refer to the Stipulated Facts for Purposes of Cypress' Motion for Summary Judgment of Noninfringement, which is attached as exhibit 11 to the Brown Declaration, Dkt. No. 51.

**RESPONSE: Undisputed.**

16. SUPREP is listed by the FDA in the agency's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"). *See* Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022372&Product_No=001&table1=OB_Rx.

**RESPONSE: Undisputed.**

17. The Orange Book states that SUPREP is covered by the '149 patent.

**RESPONSE: Undisputed.** Cypress objects to this fact to the extent it implies the FDA has reviewed whether SUPREP is in fact "covered by" the '149 patent. *See, e.g.*, *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("The FDA, pursuant to longstanding practice and its own regulations, and based on its acknowledged lack of expertise and resources, has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders' patent declarations and following their listing instructions.")

18. The Orange Book states that the '149 patent has an expiration date of March 7, 2023. *See* Electronic Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=022372&Product_No=001&table1=OB_Rx.

**RESPONSE: Undisputed.**

**SUPREP**

19. SUPREP is sold as a kit containing two 6-ounce bottles of oral solution. *See* SF 5; Brown Decl. Ex. 10 at BRTSUP00000129-130.

**RESPONSE: Undisputed.**

20. SUPREP does not include phosphate. *See* Brown Decl. Ex. 10 at BRTSUP00000129-130.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

21. SUPREP is an oral solution. *See* Brown Decl. Ex. 10 at BRTSUP00000129-130.

**RESPONSE: Undisputed.**

22. SUPREP is an aqueous solution. *See* Brown Decl. Ex. 10 at BRTSUP00000129-130.

**RESPONSE: Undisputed.**

23. SUPREP cleanses the colon of a patient by inducing copious, watery diarrhea. SF 8.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

24. SUPREP cleanses the colon of a patient sufficiently to allow for a satisfactory colonoscopy when used as directed by the SUPREP label. *See* Brown Decl. Ex. 10 at BRTSUP00000129.

**RESPONSE: Undisputed.**

25. According to the FDA-approved label for SUPREP, each 6 ounce bottle of SUPREP must be diluted with water to 16 ounces (about 473 ml) prior to administration. *See* SF 6; Brown Decl. Ex. 10 at BRTSUP00000129-30.

**RESPONSE: Undisputed.**

26. The sodium sulfate, potassium sulfate, and magnesium sulfate in SUPREP provide sulfate anions, which are poorly absorbed in the human body. *See* Brown Decl. Ex. 10 at BRTSUP00000136.

**RESPONSE: Undisputed for purposes of Cypress' motion.**

27. The SUPREP label states that the osmotic effect of the unabsorbed ions in SUPREP will produce a copious, watery diarrhea. *See* Brown Decl. Ex. 10 at BRTSUP00000136.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

28. SUPREP, administered according to its FDA-approved label, directs the patient to consume one 16 ounce container (about 473 ml each) of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in two separate administrations during the treatment period. SF 35.

**RESPONSE: Disputed.** The SUPREP label speaks for itself and directs the patient to consume ***two*** 16 ounce containers (about 473 ml each for a total of about 946 ml) of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution during the treatment period. Brown Decl. Ex. 10 (Dkt 51-10) at BRTSUP00000130; SF35.

29. The SUPREP label instructs patients to dilute one 6 ounce bottle of solution with 10 ounces of water to 16 ounces before drinking the solution. *See* Brown Decl. Ex. 10 at BRTSUP00000130.

**RESPONSE: Undisputed**, but Cypress objects to BMF 29 because it is an incomplete description of the administration of SUPREP. The SUPREP label instructs patients to consume ***two*** 6 ounce containers of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution diluted with water to 16 ounces each, administered according to a split-dose (two day) regimen. Brown Decl. Ex. 10 (Dkt 51-10) at BRTSUP00000130. The SUPREP label further states that "[t]he dose for colon cleansing requires administration of two bottles of SUPREP Bowel Prep Kit." *Id.*

30. Ingestion of one 6 ounce bottle of SUPREP diluted with water to 16 ounces (about 473 ml) causes a patient to have copious, watery diarrhea. SF 7.

**RESPONSE: Undisputed for purposes of Cypress' motion.**

31. The SUPREP label instructs patients to ingest one 6 ounce bottle diluted with water to 16 ounces the day of the colonoscopy. *See* Brown Decl. Ex. 10 at BRTSUP00000130.

**RESPONSE: Disputed** to the extent BMF 31 implies that the SUPREP label instructs patients to ingest ***only one*** 6 ounce bottle diluted with water to 16 ounces. The SUPREP label, which speaks for itself, instructs patients to consume the first 6 ounce bottle diluted with water to 16 ounces "the evening prior to colonoscopy," and the *second* 6 ounce bottle diluted with water to 16 ounces "the morning of colonoscopy (10 to 12 hours after the evening dose)," for a total administration of 32 ounces, or approximately 946 mls. Brown Decl. Ex. 10 (Dkt 51-10) at BRTSUP00000130.

32. The SUPREP label instructs patients to ingest a second 6 ounce bottle diluted with water to 16 ounces the morning before colonoscopy. *See* Brown Decl. Ex. 10 at BRTSUP00000130.

**RESPONSE: Disputed** to the extent BMF 32 differs from the instructions in the SUPREP label, which speaks for itself. The SUPREP label instructs patients to consume the first 6 ounce bottle diluted with water to 16 ounces "the evening prior to colonoscopy," and the *second* 6 ounce bottle diluted with water to 16 ounces "the morning of colonoscopy (10 to 12 hours after the evening dose), for a total administration of 32 ounces, or approximately 946 mls." Brown Decl. Ex. 10 (Dkt 51-10) at BRTSUP00000130.

33. SUPREP was approved by the FDA and was found to be safe and effective for use as a colonoscopy preparation. *See* Brown Decl. Ex. 8 (SUPREP NDA Approval Letter).

**RESPONSE: Undisputed** to the extent that the approved indication is "for cleansing of the colon in preparation for colonoscopy in adults."

34. Cypress does not contest that administration of SUPREP according to its FDA approved label will not cause clinically significant electrolytes in at least one patient. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-14 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE: Undisputed for purposes of Cypress' motion.**

**Cypress' Abbreviated New Drug Application**

35. Cypress is the owner of Abbreviated New Drug Application ("ANDA") No. 204135, for a generic copy of Braintree's SUPREP drug product.

**RESPONSE: Undisputed**, however, Cypress objects to BMF 35 to the extent it argumentatively refers to Cypress' ANDA Product as a "generic copy" of Braintree's SUPREP drug product.

36. On July 31, 2013, Cypress sent Braintree a Paragraph IV Letter stating that in Cypress' view, each of the claims of the '149 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, sale, offer for sale, or importation of its proposed generic product. Brown Decl. Ex. 9 at CYPRESS000068; Dkt. 1 (Braintree's Complaint).

**RESPONSE:** **Disputed** to the extent Braintree incorrectly recites the date of Cypress' Paragraph IV Letter to Braintree as "July 31, 2013," however, this fact is ***irrelevant*** to Cypress' Motion for Summary Judgment of Noninfringement.

37. Cypress submitted its ANDA No. 204135 to the FDA on March 15, 2012. SF 10.

**RESPONSE:** **Undisputed.**

38. Cypress has stipulated that the information and statements contained in Cypress' ANDA No. 204135 are true and accurate. SF 11.

**RESPONSE:** **Undisputed.**

39. Cypress was aware of the '149 patent when it submitted ANDA No. 204135. *See* Brown Decl. Ex. 9 at CYPRESS000068.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.**

40. Cypress' ANDA No. 204135 describes the composition, dosage form, and route of administration of Cypress' proposed generic version of SUPREP. SF 12.

**RESPONSE:** **Undisputed.**

41. Cypress' proposed generic version of SUPREP is named Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution. *See* Brown Decl. Ex. 9 at CYPRESS000068.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.**

42. Cypress' proposed generic version of SUPREP has the same composition, dosage form, and route of administration as Braintree's SUPREP. SF 13.

**RESPONSE:** **Undisputed.**

43. Cypress' proposed generic version of SUPREP is bioequivalent to Braintree's SUPREP. SF 14.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

44. Cypress' proposed generic version of SUPREP is pharmaceutically equivalent to SUPREP. SF 15.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

45. Cypress' proposed generic version of SUPREP is therapeutically equivalent to SUPREP. SF 16.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

46. Cypress' proposed generic version of SUPREP contains the same ingredients at the same concentration levels as SUPREP. SF 17.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

47. Cypress' proposed generic version of SUPREP contains the same active ingredients in the same concentration as SUPREP. SF 18.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

48. Cypress' proposed generic version of SUPREP is an osmotic laxative containing sodium sulfate, potassium sulfate and magnesium sulfate. SF 19.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

49. Cypress' proposed generic version of SUPREP will, upon approval, be indicated for cleansing of the colon in preparation for colonoscopy in adults. SF 20.

**RESPONSE: Undisputed.**

50. Braintree filed suit against Cypress for infringement of the '149 patent pursuant to 35 U.S.C. §271(e)(5) on September 11, 2012. Dkt. No. 1 (Braintree's Complaint).

**RESPONSE:** **Undisputed** that Braintree filed suit against Cypress for infringement of the '149 patent on September 11, 2012, but the suit was brought pursuant to 35 U.S.C. §271(e)(2).

**Cypress' Proposed Generic Product**

51. Cypress' proposed generic version of SUPREP cleanses the colon of a patient by inducing copious, watery diarrhea in a patient. SF 21.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.** Moreover, SF21 reads "Cypress' proposed generic version of SUPREP cleanses the colon of a patient by *causing the patient to have* copious, watery diarrhea."

52. Cypress' proposed generic version of SUPREP would be sold as a kit containing two 6-ounce bottles of oral solution. SF 22.

**RESPONSE:** **Undisputed.**

53. According to the proposed label for Cypress' proposed generic version of SUPREP, each 6 ounce bottle of Cypress' generic version of SUPREP must be diluted with water to 16 ounces prior to administration. SF 23.

**RESPONSE:** **Undisputed.**

54. Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24.

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' motion.**

55. Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the *Novel Case*. SF 25.

**RESPONSE: Undisputed for purposes of Cypress' motion, but irrelevant.**

56. Each 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains an effective amount of $Na_2SO_4$, an effective amount of $MgSO_4$, and an effective amount of $K_2SO_4$ for inducing a copious, watery diarrhea in a patient. SF 26.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

57. One 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains about 473 milliliters of an aqueous hypertonic solution. SF 27.

**RESPONSE: Undisputed.**

58. 473 milliliters is between about 100 milliliters and about 500 milliliters.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion** since Cypress' proposed ANDA label does not direct anyone to ingest only one bottle of its two-bottle product.

59. The proposed label for Cypress' proposed generic version of SUPREP contained in ANDA No. 204135 is the same, in all relevant and material respects, as Braintree's FDA approved label for SUPREP. SF 28.

**RESPONSE: Undisputed.**

60. The proposed label for Cypress' proposed generic version of SUPREP contained in ANDA No. 204135 describes the dosing regimen of Cypress' proposed generic version of SUPREP. SF 29.

**RESPONSE: Undisputed.**

61. The proposed label for Cypress' proposed generic version of SUPREP contained in ANDA No. 204135 instructs healthcare professionals how to prescribe and patients how to use Cypress' proposed generic version of SUPREP. SF 30.

**RESPONSE: Undisputed.**

62. Cypress intends for healthcare professionals to prescribe Cypress' proposed generic version of SUPREP for use according to the proposed label contained in ANDA No. 204135. SF 31.

**RESPONSE: Undisputed.**

63. Cypress intends for patients to use Cypress' proposed generic version of SUPREP according to the proposed label contained in ANDA No. 204135. SF 32.

**RESPONSE: Undisputed.**

64. The proposed labeling for Cypress' proposed generic version of SUPREP states: "The dose for colon cleansing requires administration of two bottles of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit." SF 33.

**RESPONSE: Undisputed.**

65. Cypress' proposed generic version of SUPREP, administered according to its proposed label, directs the patient to consume one 16 ounce containers (about 473 ml each) of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in two separate administrations during the treatment period. SF 34.

**RESPONSE: Disputed.** The proposed label for Cypress' proposed generic version of SUPREP, which speaks for itself, directs the patient to consume ***two*** 16 ounce containers (about 473 ml each for a total of about 946 ml) of sodium sulfate,

potassium sulfate, and magnesium sulfate aqueous solution during the treatment period. Dkt 46-1 at CYPRESS000038; SF34.

66. Cypress' proposed generic version of SUPREP will cleanse the colon of a patient sufficiently to allow for a satisfactory colonoscopy when used as directed by the proposed label contained in ANDA No. 204135. SF 36.

**RESPONSE: Undisputed.**

67. Cypress' proposed generic product will, like SUPREP, induce colonic purgation if taken as directed by the proposed label contained in ANDA No. 204135. SF 37.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

68. Cypress' proposed generic version of SUPREP cleanses the colon of a patient by inducing purgation of fecal matter from the colon, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 38.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

69. Cypress' proposed generic version of SUPREP cleanses the colon of a patient by inducing copious, watery diarrhea in a patient. SF 39.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Moreover, SF 39 reads "Cypress' proposed generic version of SUPREP cleanses the colon of a patient by *causing the patient to have* copious, watery diarrhea."

70. According to its proposed label, Cypress' generic version of SUPREP will be administered according to a split-dose regimen. SF 40.

**RESPONSE: Undisputed.**

71. Drinking the second 6 ounce bottle of Cypress' generic version of SUPREP, diluted to 16 ounces with water, 10 to 12 hours after drinking the first bottle, will cause a patient

to have additional copious, watery diarrhea and allow cleansing of the colon in preparation for colonoscopy in adults. SF 41.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

72. The document Bates numbered CYPRESS000124-CYPRESS000168 is a side-by-side comparison of the FDA-approved label for Braintree's SUPREP drug product and the proposed label for Cypress' proposed generic version of SUPREP. SF 42.

**RESPONSE: Undisputed.**

73. The document Bates numbered CYPRESS000124-CYPRESS000168 identifies all changes between the FDA-approved label for Braintree's SUPREP and the proposed label for Cypress' proposed generic version of SUPREP. SF 43.

**RESPONSE: Undisputed.**

74. Cypress has not performed any clinical studies in human subjects with Cypress' proposed generic version of SUPREP. SF 44.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Moreover, SF 44 reads "*[a]s permitted by law*, Cypress has not performed any clinical studies in human subjects with Cypress' proposed generic version of SUPREP."

75. Cypress relies on Braintree's clinical data for SUPREP in ANDA No. 204135. SF 45.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Moreover, SF 45 reads "*[a]s permitted by law*, Cypress relies on Braintree's clinical data for SUPREP in ANDA No. 204135."

76. Cypress did not submit any data to the FDA showing that Cypress' proposed generic version of SUPREP causes any clinically significant electrolyte shifts in patients. SF 46.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

77. Cypress does not contest that administration of its proposed generic version of SUPREP according to its proposed label will not cause clinically significant electrolytes in at least one patient. Dkt. No. 41, ¶¶ 3, 6-7; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-14 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

**The *Novel* Case**

78. Braintree filed suit against Novel, the owner of ANDA No. 202511 for a generic version of Braintree's SUPREP, for infringement of the '149 patent pursuant to 35 U.S.C §271(e)(5) on March 9, 2011. *See Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., case no. 11-01341 ("the *Novel Case*") D.I. 1.

**RESPONSE: Undisputed** that Braintree filed suit against Novel, the owner of ANDA No. 202511 for a generic version of Braintree's SUPREP, for infringement of the '149 patent on March 9, 2011, but the suit was brought pursuant to 35 U.S.C. §271(e)(2).

79. Cypress' proposed generic product is, in all relevant and material aspects, identical to Novel's proposed generic version of Braintree's SUPREP that was adjudged to infringe the '149 patent in the *Novel Case*. See Dkt. No. 41 at ¶ 7.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

80. The Honorable U.S. District Court Judge Peter Sheridan presided over the *Novel* Case.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

81. In the *Novel* case, Judge Sheridan addressed, among other issues, claim construction, infringement, and validity of the '149 patent.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

82. In the *Novel Case*, Judge Sheridan construed the meaning of the disputed claim terms in the '149 patent as follows:

(a) "**Purgation**" means "an evacuation of a copious amount of stool from the bowels after oral administration of the solution."

(b) "**Aqueous hypertonic solution**" means "a water based mixture of poorly absorbable sulfate salts that creates an osmotic pressure gradient between the bowel and bodily fluids large enough to induce the movement of water from the body into the bowel and thereby produce a purgation."

(c) "**Clinically significant**" means "alterations [in] blood chemistry that are outside the normal upper or lower limits of their range or other untoward effects."

(d) "**An effective amount**" means "the amount and combination of salts necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts."

*See* Brown Decl. 6, at 11 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Cypress objects to BMF 82 to the extent it implies that the claim terms disputed in the *Novel Case* are the same terms that are disputed in the instant case. Judge Sheridan's construction of the claim terms at issue in the *Novel Case* is ***irrelevant*** to Cypress' Motion, which relates only to the "from about 100 ml to about 500 ml" limitation present in every asserted claim of the '149 patent. Dkt. 41 ¶3.

83. In the *Novel* Case, Novel argued that purgation means "cleansing". *See* Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

84. Judge Sheridan rejected Novel's proposed construction of "purgation," reasoning that "the term 'cleanse' is never used in the language of claims 15 and 18" and that "when enumerating the claims, the inventors were being more precise with their use of 'purgation.'" *See* Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE:** **Undisputed** that the quoted phrases appear in the cited Order on Claim Construction in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF 84 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 84 to the extent it implies the reasoning in Judge Sheridan's opinion is controlling in this case. Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See Ivan Visin Shipping, Ltd. v. Onego Shipping & Chartering B.V.*, 543 F. Supp. 2d 338, 339 (S.D.N.Y. 2008) (Rakoff, J.); *see* Dkt. 41 ¶¶3, 5.

85. Judge Sheridan explained that "[a]lthough cleansing is a term used in the specification of the '149 Patent, claims 15 and 18 clearly adopt purgation as the methodology to improve visualization of the colon." *See* Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).

**RESPONSE:** **Undisputed** that the quoted phrases appear in the cited Order on Claim Construction in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF 85 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 85 to the extent it implies the reasoning in Judge Sheridan's opinion is controlling in this case. Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See*

*Ivan Visin Shipping, Ltd. v. Onego Shipping & Chartering B.V.*, 543 F. Supp. 2d 338, 339 (S.D.N.Y. 2008) (Rakoff, J.); *see* Dkt. 41 ¶¶ 3, 5.

86. The term "purgation" does not mean the same thing as the term "cleansing." *See* Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction); Dkt. No. 41 at ¶ 5.

**RESPONSE:** No response is required regarding the meaning of claim terms since such a determination is not a fact, but a legal conclusion.

87. Judge Sheridan concluded that the '149 patent was valid and infringed by Novel's proposed generic copy of SUPREP. *See* Dkt. No. 46-15 (*Novel Case* Summary Judgment Decision); Brown Decl., Ex. 5 (*Novel Case* Decision on Validity).

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' Motion.**

88. Judge Sheridan granted Braintree's Motion for Summary Judgment of Infringement of the '149 patent by Novel. *See* Dkt. No. 46-15 (*Novel Case* Summary Judgment Decision).

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' Motion.**

89. Judge Sheridan denied Novel's Motion for Summary Judgment of Non-Infringement of the '149 patent, finding that Novel's proposed generic copy of SUPREP infringes the claims of the '149 patent and that its proposed label induces infringement. *See* Dkt. No. 46-15 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Undisputed, but irrelevant for purposes of Cypress' Motion.**

90. Judge Sheridan's opinion stated that although "Novel's copy of SUPREP requires that a patient ingest 'two bottles of oral solution,'" "each [bottle] will be 6 ounces diluted

to 16 ounces when consumed." *See* Dkt. No. 46-15 at 17 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Undisputed** that the quoted phrases appear in the cited Opinion in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF 90 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 90 to the extent it implies Judge Sheridan's opinion is controlling in this case. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 329 (1971). Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See Ivan Visin Shipping, Ltd. v. Onego Shipping & Chartering B.V.*, 543 F. Supp. 2d 338, 339 (S.D.N.Y. 2008) (Rakoff, J.); *see* Dkt. 41 ¶¶ 3.

91. Judge Sheridan's opinion stated that "[g]iven that one bottle is sufficient to induce purgation, there is no genuine dispute that the Generic Product constitutes a composition of from about 100 ml to about 500 ml of an aqueous hypertonic solution, as required by the claims." *See* Dkt. No. 46-15 at 17 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Undisputed** that the quoted phrase appears in the cited Opinion in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF 91 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 91 to the extent it implies Judge Sheridan's opinion is controlling in this case. *See Blonder-Tongue*, 402 U.S. at 329. Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See Ivan Visin Shipping*, 543 F. Supp. 2d at 339; *see* Dkt. 41 ¶ 3.

92. Judge Sheridan's opinion stated that "Novel's proposed label instruct patients to drink two bottles of solution both the evening before colonoscopy and the day of colonoscopy. That is, the Generic Product – which infringes claims 15 and 18 – will be orally administered twice (in two bottle) during a treatment period." *See* Dkt. No. 46-15 at 19 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Undisputed** that the quoted phrase, with the change to "(two bottle**s**)," appears in the cited Opinion in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Dkt. 46-15 at 19. Cypress objects to BMF 92 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 92 to the extent it implies Judge Sheridan's opinion is controlling in this case. *See Blonder-Tongue*, 402 U.S. at 329. Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See Ivan Visin Shipping*, 543 F. Supp. 2d at 339; *see* Dkt. 41 ¶ 3.

93. Judge Sheridan found that administration of both diluted bottles of Novel's proposed generic copy of SUPREP according to the instructions on Novel's proposed label (to achieve the goal of colon cleansing in preparation for a colonoscopy) would constitute two distinct acts of infringement of the '149 patent claims. *See* Dkt. No. 46-15 at 19 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Disputed** because MF92 is an ambiguous and incomplete characterization of the Opinion in the *Novel Case*, but irrelevant for purposes of Cypress' motion. *See* Dkt. No. 46-15 at 19. Cypress further objects to BMF 93 to the extent it implies Judge Sheridan's opinion is controlling in this case. *See Blonder-Tongue*, 402 U.S. at 329. Judge Sheridan's reasoning is relevant only to the extent this

Court finds it persuasive. *See Ivan Visin Shipping*, 543 F. Supp. 2d at 339; *see* Dkt. 41 ¶ 3.

94. Judge Sheridan rejected Novel's argument that Braintree had made supposed "admissions" to the United States Patent and Trademark Office ("PTO") and in publications that the volume of SUPREP is 946 milliliters, or two bottles each diluted to 16 ounces (473). Judge Sheridan stated that "these alleged admissions do nothing to contradict the fact that…one bottle of SUPREP is sufficient to cause purgation of the colon." *See* Dkt. No. 46-15 at 17 (*Novel Case* Summary Judgment Opinion).

**RESPONSE:** **Disputed, but irrelevant for purposes of Cypress' motion.** Judge Sheridan's Opinion in the *Novel Case* states, in relevant part, "Novel argues that Braintree has admitted to the PTO and in publications co-authored by one of the'149 patent inventors that the volume of SUPREP solution ***needed for inducing purgation*** of the colon is 946 milliliters." Dkt. No. 46-15 at 17 (emphasis added). Cypress further objects to BMF 94 because Judge Sheridan's reasoning on this point is ***irrelevant*** to Cypress' Motion, which explains that Braintree's admissions to the PTO are binding statements that ***both bottles*** of SUPREP (or a generic equivalent) are relevant to infringement of the "about 100 to about 500 ml" volume limitation present in each asserted claim.

95. Judge Sheridan rejected Novel's argument that administration of one diluted bottle of SUPREP to cause purgation is an "off-label use", and therefore cannot infringe the claims of the '149 patent under the *Warner-Lambert* case and its progeny. *See* Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion).

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Cypress objects to BMF 95 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. BMF 95 is ***irrelevant*** to Cypress' Motion because the argument made in Cypress' Motion—that administration of ***only a single bottle*** to induce purgation short of the FDA-approved indication for cleansing the colon in preparation for colonoscopy is not contemplated by Cypress' proposed label—is a distinct argument from that made by the defendants in the *Novel Case*. *Compare* Dkt. 43 at 21 *with* Dkt. 46-15 at 16.

96. Judge Sheridan found that Novel's "off-label use argument" was "without merit." *See* Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion).

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.** Cypress objects to BMF 96 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. BMF 96 is ***irrelevant*** to Cypress' Motion because the argument made in Cypress' Motion—that administration of ***only a single bottle*** to induce purgation short of the FDA-approved indication for cleansing the colon in preparation for colonoscopy is not contemplated by Cypress' proposed label—is a distinct argument from that made by the defendants in the *Novel Case*. *Compare* Dkt. 43 at 21 *with* Dkt. 46-15 at 16.

97. Judge Sheridan issued his decision that Novel's proposed generic copy of SUPREP infringes the '149 patent claims after briefing on both Braintree's Motion for Summary Judgment of Infringement, briefing on Novel's Motion for Summary Judgment of Noninfringement, and oral argument on those two motions. *See Novel Case*, Dkt. Nos. 143, 159, 173, 176, 203, 207.

**RESPONSE: Undisputed, but irrelevant for purposes of Cypress' motion.**

98. Judge Sheridan stated that "[b]ecause purgation is the method by which SUPREP achieves the FDA-approved indication of colon cleansing, purgation cannot be an off-label use for SUPREP." *See* Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion); *see also* Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction) (finding that "claims 15 and 18 clearly adopt purgation as the methodology to improve visualization of the colon").

**RESPONSE: Undisputed** that the quoted phrases appear in the cited Opinion and Order on Claim Construction in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF 98 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. BMF 98 is ***irrelevant*** to Cypress' Motion because the argument made in Cypress' Motion—that administration of ***only a single bottle*** to induce purgation short of the FDA-approved indication for cleansing the colon in preparation for colonoscopy is not contemplated by Cypress' proposed label—is a distinct argument from that made by the defendants in the *Novel Case*. *Compare* Dkt. 43 at 21 *with* Dkt. 46-15 at 16.

99. Judge Sheridan stated that *Warner-Lambert* and its progeny "provide no guidance to the Court with respect to drug composition claims, such as claims 15 and 18 [of the '149 patent]" because "nothing in the cited cases addresses the fact that here, Novel intends to make, offer to sell, and sell a product that directly infringed the '149 patent." *See* Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion).

**RESPONSE: Undisputed** that the quoted phrases appear in the cited Opinion in the *Novel Case*, but irrelevant for purposes of Cypress' motion. Cypress objects to BMF

99 because it is incomplete and quotes portions of Judge Sheridan's opinion out of context. Cypress further objects to BMF 99 to the extent it implies Judge Sheridan's opinion is controlling in this case. *See Blonder-Tongue*, 402 U.S. at 329. Judge Sheridan's reasoning is relevant only to the extent this Court finds it persuasive. *See Ivan Visin Shipping*, 543 F. Supp. 2d at 339; *see* Dkt. 41 ¶ 3.

**Cypress' Proposed Generic Product Will Infringe the '149 Patent**

100. The following infringement claim chart shows that Cypress' proposed generic version of SUPREP infringes, directly or indirectly, literally or by inducement, claims 15, 18-20 and 23 of the '149 patent:

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| 15 | A composition for inducing purgation of the colon in a patient | Cypress' proposed label explains that its product will cause "a copious watery diarrhea," which Cypress has stipulated is a "purgation." Dkt. No. 46-1 at CYPRESS000018; SF 24-26, 37, 38.<br><br>Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the *Novel Case*. SF 25.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution | Cypress' proposed generic version of SUPREP is an aqueous hypertonic solution. *See* SF 27.<br><br>Cypress' copy of SUPREP requires that a patient ingest one bottle of oral solution diluted to 16 ounces in two separate administrations. SF 22-23, 33-35.<br><br>One 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains about 473 milliliters of an aqueous hypertonic solution. SF 27.<br><br>Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 25. |
| | comprising an effective amount of $Na_2SO_4$, an effective amount of $MgSO_4$, and | Each 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains an effective amount of $Na_2SO_4$, an effective amount of $MgSO_4$, and an effective amount of $K_2SO_4$ for inducing a patient to have a copious, watery diarrhea. SF 26; *see also* Dkt. No. 46-1 at CYPRESS000018.<br><br>The active ingredients of Cypress' proposed generic copy of SUPREP |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| | an effective amount of $K_2SO_4$ | are "sodium sulfate, potassium sulfate, and magnesium sulfate." *See* Brown Decl. Ex. 9 at CYPRESS000205.<br><br>The combination of these three sulfate salts "causes a patient to have a copious, watery diarrhea," which is purgation as defined by the Court. *See, e.g.,* SF 26; *see also* Dkt. No. 46-1 at CYPRESS000018.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 17-18 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | wherein the composition does not produce any clinically significant electrolyte shifts | Cypress does not contest that administration of its proposed generic version of SUPREP, according to its proposed label will not cause clinically significant electrolytes in at least one patient. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-14 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-14 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | and does not include phosphate | Cypress' proposed label does not list phosphate as an ingredient in its proposed product. *See* Brown Decl. Ex. 9 at CYPRESS000208. Thus, Cypress' proposed generic version of SUPREP does not contain phosphate.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 18 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| 18 | A composition for inducing purgation of the colon in a patient | Cypress' proposed label explains that its product will cause "a copious watery diarrhea," which Cypress has stipulated is a "purgation." Dkt. No. 46-1 at CYPRESS000018; SF 24-26, 37, 38.<br><br>Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 25.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 16 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution | Cypress' proposed generic version of SUPREP is an aqueous hypertonic solution. *See* SF 27.<br><br>Cypress' copy of SUPREP requires that a patient ingest one bottle of oral solution diluted to 16 ounces in two separate administrations. SF 22-23, 33-35.<br><br>One 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains about 473 milliliters of an aqueous hypertonic solution. SF 27.<br><br>Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 25. |
| | consisting essentially of an effective amount of $Na_2SO_4$, an effective amount of | Each 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces contains an effective amount of $Na_2SO_4$, an effective amount of $MgSO_4$, and an effective amount of $K_2SO_4$ for inducing a patient to have a copious, watery diarrhea. SF 26; *see also* Dkt. No. 46-1 at CYPRESS000018.<br><br>The active ingredients of Cypress' proposed generic copy of SUPREP |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| | $MgSO_4$, and an effective amount of $K_2SO_4$ | are "sodium sulfate, potassium sulfate, and magnesium sulfate." *See* Brown Decl. Ex. 9 at CYPRESS000205.<br><br>The combination of these three sulfate salts "causes a patient to have a copious, watery diarrhea," which is purgation as defined by the Court. *See, e.g.,* SF 26; *see also* Dkt. No. 46-1 at CYPRESS000018.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 17-18 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | wherein the composition does not produce any clinically significant electrolyte shifts | Cypress does not contest that administration of its proposed generic version of SUPREP, according to its proposed label will not cause clinically significant electrolytes in at least one patient. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-14 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction).<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 12-16 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |
| | and does not include phosphate | Cypress' proposed label does not list phosphate as an ingredient in its proposed product. *See* Brown Decl. Ex. 9 at CYPRESS000208. Thus, Cypress' proposed generic version of SUPREP does not contain phosphate.<br><br>Cypress has waived any argument that its product does not meet this limitation of the asserted claims of the '149 patent. Dkt. No. 41, ¶¶ 3, 6-8; SF 44-46; Brown Decl., Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript); Dkt. No. 46-15 at 18 (*Novel Case* Summary Judgment Opinion); Brown Decl., Ex. 6, at 6 (*Novel Case* Dkt. No. 130, Order on Claim Construction). |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| 19 | A method for inducing colonic purgation in a patient, comprising the steps of:<br><br>(a) orally administering an effective amount of the composition of claim 18 to a patient; and | Cypress' proposed label instructs patients to take one bottle of its copy of SUPREP twice during the treatment period, once in the evening the day prior to colonoscopy and once the day of colonoscopy. *See* Dkt. No. 46-1 at CYPRESS000007-8.<br><br>Cypress' proposed generic copy of SUPREP includes an effective amount of the composition of claim 18, because administration of one bottle of its proposed product induces purgation of the colon of a patient without causing clinically significant electrolyte shifts. *See supra*, chart for claim 18.<br><br>Cypress admits that its generic copy of SUPREP will be sold with a proposed product label and package insert that are copied from Braintree's FDA-approved label. SF 27. Cypress' proposed label describes the dosing regimen of Cypress' proposed generic version of SUPREP. SF 29.<br><br>Cypress intends for both doctors and patients to use Cypress' proposed generic product according to its proposed product label and package insert. SF 29-32.<br><br>Cypress' proposed product is an oral solution. SF 22, 27. |
| | (b) allowing the administered composition to induce colonic purgation. | Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 25.<br><br>Cypress' proposed label explains that administration of one bottle of its product will cause "a copious watery diarrhea," which Cypress has stipulated is a "purgation." Dkt. No. 46-1 at CYPRESS000018; SF 24-26, 37, 38.<br><br>The label for Cypress' proposed generic product instructs patients and doctors to orally administer Cypress' proposed product and allow the product to cause colonic purgation. *See* SF 29-33; Dkt. No. 46-1 at CYPRESS000007-8, 18. |
| 20 | A method for inducing colonic purgation in | Cypress' proposed label instructs patients to take one bottle of its copy of SUPREP twice during the treatment period, once in the evening the day prior to colonoscopy and once the day of colonoscopy. *See* Dkt. No. 46-1 at CYPRESS000007-8. |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| | a patient, comprising the steps of:<br><br>(a) orally administering an effective amount of the composition of claim 15 to a patient; and | Cypress' proposed generic copy of SUPREP includes an effective amount of the composition of claim 15, because administration of one bottle of its proposed product induces purgation of the colon of a patient without causing clinically significant electrolyte shifts. *See supra*, chart for claim 15.<br><br>Cypress admits that its generic copy of SUPREP will be sold with a proposed product label and package insert that are copied from Braintree's FDA-approved label. SF 27. Cypress' proposed label describes the dosing regimen of Cypress' proposed generic version of SUPREP. SF 29.<br><br>Cypress intends for both doctors and patients to use Cypress' proposed generic product according to its proposed product label and package insert. SF 29-32.<br><br>Cypress' proposed product is an oral solution. SF 22, 27. |
| | (b) allowing the administered composition to induce colonic purgation. | Drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will cause a patient to have copious, watery diarrhea. SF 24. Thus, drinking one 6 ounce bottle of Cypress' proposed generic version of SUPREP diluted with water to 16 ounces will induce purgation of fecal matter from the colon of a patient, under the construction of the term "purgation" adopted by the U.S. District Court in the Novel Case. SF 25.<br><br>Cypress' proposed label explains that administration of one bottle of its product will cause "a copious watery diarrhea," which Cypress has stipulated is a "purgation." Dkt. No. 46-1 at CYPRESS000018; SF 24-26, 37, 38.<br><br>The label for Cypress' proposed generic product instructs patients and doctors to orally administer Cypress' proposed product and allow the product to cause colonic purgation. *See* SF 29-33; Dkt. No. 46-1 at CYPRESS000007-8, 18. |
| 23 | A method for inducing colonic purgation in a patient according to claim 20, | Cypress will induce infringement of claim 20 for the reasons stated above. |
| | wherein the | Cypress' proposed labeling induces infringement of claim 23. *See* Dkt. |

| Claim Number | Claim Element | Proof of Infringement |
|---|---|---|
| | effective amount of the composition is administered in two or more doses within a treatment period. | No. 46-1 at CYPRESS000007-8; SF 31-34.<br><br>Cypress' proposed label instructs patients to practice claim 20 twice. SF 31-34; *see* Dkt. No. 46-1 at CYPRESS000007-8 (instructing patients to take a second dose the "morning of the colonoscopy (10 to 12 hours *after the evening dose*") (emphasis added).<br><br>Cypress' proposed label instructs patients to take one bottle of its copy of SUPREP twice during the treatment period, once in the evening the day prior to colonoscopy and once the day of colonoscopy. *See* Dkt. No. 46-1 at CYPRESS000007-8.<br><br>Cypress' proposed generic copy of SUPREP includes an effective amount of the composition of claim 18, because administration of one bottle of its proposed product induces purgation of the colon of a patient without causing clinically significant electrolyte shifts. *See supra*, chart for claim 18.<br><br>Cypress admits that its generic copy of SUPREP will be sold with a proposed product label and package insert that are copied from Braintree's FDA-approved label. SF 27. Cypress' proposed label describes the dosing regimen of Cypress' proposed generic version of SUPREP. SF 29.<br><br>Cypress intends for both doctors and patients to use Cypress' proposed generic product according to its proposed product label and package insert. SF 29-32. |

**RESPONSE:** **Disputed.** Cypress objects to BMF 100 because it is not a "short and concise statement" of a "material fact" but rather a legal conclusion that is the very subject of Cypress' Motion for Summary Judgment of Noninfringement. *See* L. Civ. R. 56.1. Cypress further objects to BMF 100 to the extent it recites stipulated facts and evidence that are ***irrelevant*** to Cypress' Motion, which relates only to the "about 100 ml to about 500 ml" limitation present in every asserted claim of the '149 patent. *See* Dkt. 41 ¶ 3.

Dated: August 13, 2013

Respectfully submitted,

*/s/ Lisa N. Phillips*
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**CERTIFICATE OF SERVICE**

I hereby certify that on August 13, 2013, a true and correct copy of the foregoing **DEFENDANT CYPRESS PHARMACEUTICAL, INC.'S COUNTERSTATEMENT TO PLAINTIFF BRAINTREE LABORATORIES, INC.'S RULE 56.1 STATEMENT OF MATERIAL FACTS** was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

*/s/ Erik van Leeuwen*
Erik van Leeuwen
Litigation Operations Manager
Rothwell, Figg, Ernst & Manbeck, P.C.